IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA

ABBVIE INC. (a Delaware corporation); ALLERGAN, INC. (a Delaware corporation); DURATA THERAPEUTICS, INC. (a Delaware corporation); ABBVIE PRODUCTS LLC (a Georgia limited liability company); APTALIS PHARMA US, INC. (a Delaware corporation); PHARMACYCLICS LLC (a Delaware limited liability company); ALLERGAN SALES, LLC (a Delaware limited liability company), *Plaintiffs*, v. LIZ MURRILL, in her official capacity as the Attorney General of the State of Louisiana, *Defendant*.	No. 6:23-CV-01307 Judge Robert R. Summerhays Magistrate Judge Carol B. Whitehurst

PLAINTIFFS' COMBINED OPPOSITION TO
DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT AND
REPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Act 358 is unconstitutional. Louisiana seeks to impose, as a matter of state law, the same expansive interpretation of the federal 340B statute that it tried and failed to persuade the Third Circuit to adopt. This Court should reject Louisiana's attempt to insert itself into a federal program, take private property, and subject regulated parties to vague and arbitrary laws. Defendants' opposition briefs do nothing to salvage the statute from those problems.

Start with preemption: In her brief, the Attorney General effectively concedes that Act 358 seeks to alter the conditions of participation in federal Medicare and Medicaid programs. As her brief puts it, Act 358 imposes "separate requirements," above and beyond those prescribed by Congress, that manufacturers participating in the federal 340B program must abide by in Louisiana. Opp. at 17. That is tantamount to a confession that Act 358 is preempted. The federal 340B program is a wholly federal creation—a condition of manufacturers' voluntary participation in Medicare and Medicaid. States cannot raise the price of admission to federal programs above the level Congress has set. Yet that is precisely what Act 358 does: In addition to offering 340B-discounted drugs to statutorily enumerated covered entities, as federal law requires, under Act 358 manufacturers must *also* transfer their drugs at below-market prices to a host of for-profit commercial pharmacies. And even though federal law establishes an exclusive administrative enforcement mechanism for claims of overcharges, *Astra USA, Inc. v. Santa Clara Cnty., Cal.*, 563 U.S. 110, 114, 119–21 (2011), the Attorney General's Answer, ECF No. 20, concedes *fifteen times* that Act 358 creates Louisiana's own remedy for alleged overcharges.

Louisiana tries to avoid preemption by recasting Act 358 as a law governing the delivery of drugs rather than expanding who gets the benefits of federal 340B pricing. That effort fails. It runs headlong into the Attorney General's own admissions in her Answer, ECF No. 20, and squarely contradicts the law and the undisputed facts. There is no dispute that pharmacies in

Louisiana can and do obtain as much of manufacturers' drugs as their customers require. The only dispute is over price—namely, whether for-profit pharmacies are entitled to access manufacturers' drugs at the federally discounted 340B price, sell the drugs to their customers at the regular price, and pocket the difference after splitting arbitrage proceeds with covered entities. Precisely because the federal 340B statute does not grant pharmacies any right to participate in the 340B program, or access the drugs at the discounted price, Act 358 seeks to change the requirements of federal law.

Indeed, the Louisiana statute has *no effect* on delivery of drugs. Under the replenishment model of 340B pricing contract pharmacies dispense drugs (purchased at regular prices) from their own general inventories—*i.e.*, from the stock of drugs delivered to them through regular commercial orders *not* governed by Act 358. After subsequently attempting to match commercial-price sales to 340B patients using their own criteria, contract pharmacies seek to replenish their general inventories with additional drugs purchased at the 340B price—in other words, they retroactively change the price of drugs they purchased commercially. The only effect of Act 358 in the real world is thus to change the *price* of drugs, which federal law regulates. And it is undisputed that, as a matter of historical fact, adopting Louisiana's preferred policy entails a massive effect on the *volume* of drugs subject to 340B discounts—not how those drugs are transported from place to place. In short, Act 358 is not a delivery regulation; it is a transparent attempt to reverse the Third Circuit's interpretation of a limited federal drug pricing law. To the extent the Court believes any of that is subject to material factual dispute, the case should be opened for appropriate discovery.

Apart from preemption, however, Act 358 suffers from an entirely independent problem: It effects an unconstitutional taking by forcing a forbidden transfer of private property from one

private party (manufacturers) to another (commercial pharmacies). The Attorney General's principal defense against this claim is plainly wrong. She argues that Act 358 is not a taking because compliance with its terms is merely a condition of manufacturers' "voluntary participation" in Medicare and Medicaid. But that is not so: *Congress* sets the conditions of Medicare and Medicaid participation, and Act 358's requirements are not among those conditions. Meanwhile, Louisiana has offered AbbVie no voluntary benefit of its own to which Act 358's conditions have been attached. As a result, the voluntary participation doctrine does not save Act 358 from the Fifth Amendment.

In short, in an attempt to avoid a Takings Clause claim, the state has conceded that Act 358 is meant to be a "separate requirement[]" that Louisiana has imposed as a condition of participation in a federal program. Because Louisiana can neither impose conditions on federal spending programs nor command private parties to involuntarily give up their property without a public purpose and just compensation, Act 358 violates the Supremacy Clause and the Fifth Amendment.

The Court should grant AbbVie's motion for summary judgment and permanently enjoin enforcement of Act 358.

FACTUAL BACKGROUND

After HRSA's 2010 guidance permitting the use of unlimited contract pharmacies, the use of contract pharmacies grew and the "replenishment model" evolved to keep pace with demand. Ex. 1, April 5, 2024 Declaration of Edward Scheidler ("Scheidler Decl.") ¶ 3. Under that model, contract pharmacies do not maintain physically segregated inventories of 340B-priced drugs; instead, they place orders at market price and proceed to dispense those drugs to customers, without knowing at point-of-dispensing whether the patient is a 340B-eligible patient or not. *Id.* ¶¶ 4, 5. When a given drug reaches a sufficiently low supply, the *contract pharmacy* (or its third-party administrator ("TPA")) determines on the back end how many dispensed units of that drug

might be linked to a 340B-eligible patient. *Id.* ¶ 5. This "determination" is made based on varying criteria—for example, some contract pharmacies' replenishment eligibility criteria include prior patients who no longer receive drugs at the pharmacy, but are considered under a "once-a-patient-always-a-patient" approach, thus maintaining the contract pharmacy's eligibility to place a re-order. *See id.* The contract pharmacy, or its TPA, is then supposed to instruct the covered entity to place an order of additional quantities of that drug at the discounted price to "replenish" the contract pharmacy's inventory. *Id.* Sometimes, however, contract pharmacies place orders directly. Ex. 2, June 16, 2021 Declaration of RADM Krista M. Pedley, Director, Office of Pharmacy Affairs, HRSA, ("Pedley Decl.") ¶ 10; Ex. 1, Scheidler Decl. ¶ 5.

AbbVie or its wholesaler then ships drugs directly to the contract pharmacies, mixing without differentiation, full and 340B-priced drugs in a single shipment. Ex. 1, Scheidler Decl. ¶¶ 6, 9. The result is only a change of the overall *price* of a shipment of AbbVie drugs. *Id.* ¶ 7. Indeed, further illustrating that contract pharmacy mandates like Act 358 are about price rather than delivery, when AbbVie prohibited sales of 340B drugs to unlimited contract pharmacies, it saw a significant reduction in the volume of 340B drugs requested.[1] *Id.* ¶ 14. Its delivery methods did not change. *Id.* ¶¶ 8, 14.[2]

[1] Alternatively, the 340B program reached record heights in the decade that followed the 2010 guidance allowing for unlimited contract pharmacy use. Ex. 3, Adam J. Fein, *The 340 B Program Reached $54 Billion in 2022—up 22% vs. 2021,* Drug Channels (Sept. 24, 2023) (explaining how discounted purchases reached $53.7billion in 2022 and became the second-largest government pharmaceutical program).

[2] There is no evidence that covered entities maintain legal control of contract pharmacies' 340B "stock." To the contrary, some covered entities are moving towards a "credit" or "non-inventory" model, which would permit contract pharmacies to create a credit against their non-340B priced orders when they identify covered entity "patients" at contract pharmacies. Ex. 1, Scheidler Decl. ¶ 13. The emergence of this model evidences that 340B discounts are sometimes provided under circumstances where covered entities cannot *possibly* have maintained legal title to the dispensed drugs, and the pharmacies cannot possibly have functioned as the covered entities' legal agents.

ARGUMENT

I. ACT 358 IS PREEMPTED.

Act 358 is preempted because it unconstitutionally invades a federally regulated field and stands as an obstacle to accomplishing Congress's objectives. *See* Opening Br. at 18–35. Nothing in Defendants' opposition briefs alters that conclusion.

A. Act 358 Is Preempted Because It Intrudes On A Federally-Regulated Field And Conflicts With Congress's Objectives.

The oldest principle of Supremacy Clause jurisprudence—preexisting the modern doctrinal categories of "field" and "obstacle" preemption—is that when Congress creates a federal program to advance national objectives, States are not free to directly regulate those federal creatures. *McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 330 (1819). That fundamental principle, along with the doctrinal categories it gave life to, dooms Act 358.

The 340B program is a wholly federal creature. Congress established it and Congress made compliance with 340B a condition of participation in the federal Medicare and Medicaid programs. *See Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs.*, 58 F.4th 696, 699 (3d Cir. 2023), *judgment entered*, 2023 WL 1325507 (3d Cir. Jan. 30, 2023). The program's entire premise is that the "federal government dominates the healthcare market" and therefore "uses that market power to get drug makers to subsidize healthcare." *Id.* As relevant here, the federal 340B statute specifically regulates who is entitled to obtain 340B-discounted drugs, determines the discounted price, and establishes an exclusive set of remedies and enforcement mechanisms to police overcharges and other violations of the statute. 42 U.S.C. § 256b; *Astra USA, Inc. v. Santa Clara Cnty., Cal.*, 563 U.S. 110, 114, 119–21 (2011) (concluding that Congress intended to "centralize[] enforcement in the government" as "spreading the enforcement burden" beyond the federal scheme would frustrate Congress' purpose). The result is a regulatory field that is both

occupied by federal legislation (thereby excluding State legislative attempts to insert themselves), and planted thick with specific and carefully calibrated rules (with which any intruding State law would inevitably conflict). It should come as no surprise, therefore, that Act 358 suffers from both field and conflict preemption, as explained below.

1. Act 358 Is Field Preempted.

Act 358 impermissibly intrudes on a field of federal regulation. Not only has Congress occupied the field of 340B drugs, but Congress *created* that field and gave a federal agency exclusive authority to oversee and enforce it. *See Astra*, 563 U.S. at 114, 119-21. Because federal law defines when and under what circumstances manufacturers must transfer their drugs to others at deeply discounted prices, and because there is an exclusive cause of action and "federal remedy for overcharges that is exclusive," states have no power to supplement the federal scheme through state legislation. *See Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 11 (2003).

Astra's reasoning mirrors the Court's field preemption analysis in cases like *Arizona v. United States*, 567 U.S. 387, 403–04 (2012); *see also Astra*, 563 U.S. at 120. As *Arizona* explains, the comprehensive nature of a federal statute alone is enough to create an exclusive field of federal authority. *See* 567 U.S. at 402–03. There, the Supreme Court struck down a state law seeking to regulate United States' immigration laws where the statutory framework governing federal immigration specified (1) which categories of immigrants may be admitted to the United States, (2) created federal offenses for failure to comply with the federal scheme, (3) required registrations for immigrants once they met the necessary qualifications, and (4) provided powers to States to deny noncitizens a range of public benefits. *Id*. at 395–96. The Supreme Court held that Congress preempted the field of immigration, reasoning that the comprehensive nature of federal law was indicative of Congress's intent to design a statute that is a "harmonious whole." *Id.* at 401; *see*

also id. at 399–402 ("[Congress's] framework of regulation [is] 'so pervasive'" that Congress "left no room for the States to supplement it.").

As in *Arizona*, preemption bars any attempt to upset the balance Congress struck in the 340B context. *See id.* at 433 (Scalia, J., concurring) (explaining the Supreme Court concluded the law "would interfere with the careful balance struck by Congress"). Here, Congress created a comprehensive and exclusive statutory scheme that defines (1) what entities are eligible to participate, (2) the terms of compliance, and (3) penalties for failure to comply. Because Congress intended for 340B to be treated as a "harmonious whole," it created an exclusive field of federal authority. *Id.* at 401 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 72 (1941). It could hardly be otherwise: Congress could not force manufacturers to transfer their drugs at deeply discounted prices to third parties for their own private benefit—a constitutionally impermissible A-to-B taking—*except* as a condition of participation in federal healthcare programs. The 340B statute thus excludes any state law that seeks to impede or supplement the federal law in any way.

Louisiana's reliance on *University of Texas System v. Alliantgroup LP*, 400 F. Supp. 3d 610 (S.D. Tex. 2019), is misplaced. In *Alliantgroup*, an IRS regulation delegated authority to the Secretary of Treasury to allocate federal deductions pertaining to energy efficient commercial buildings on government property, *id.* at 617, and also prescribed which commercial buildings could receive tax deductions for its use of energy. 26 U.S.C. § 179D. Notably, the IRS regulation excluded any provisions linking it to another federal program, or an enforcement scheme for failures to comply with it. *See id.* A state law provided that a governmental entity may not disallow the allocation of federal deductions authorized by the IRS regulation, Tex. Gov't Code Ann. § 447.004(b-3), and tellingly, the State law did not seek to govern only those entities regulated by the federal IRS regulation, *Alliantgroup*, 400 F. Supp. 3d at 617. A Texas university then sued

two businesses in a dispute over the allocation of tax deductions and argued that the state law was preempted. *Id.* at 615. The district court rejected that argument for reasons wholly inapposite here. The IRS regulation at issue was, on its face, not a "comprehensive" federal program that Congress designed to operate in harmony with other federal programs. *Id.* at 617. Nor was the state law in *Alliantgroup* seeking to piggyback on the IRS regulation as Act 358 does here. *Id.* at 616–17.

2. Act 358 Is Conflict Preempted.

Act 358 also conflicts with Congress's design of the 340B program and contravenes Congress's decision to vest exclusive authority for enforcing the 340B statute in HRSA and its ADR tribunals. *Astra*, 563 U.S. at 117 ("Congress vested authority to oversee compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to covered entities."); *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372–73 (2000).

Louisiana's opposition effectively concedes that Act 358 conflicts with federal law. In response to AbbVie's takings claim, Louisiana argues that Act 358 does not unlawfully take private property because Act 358 is a condition of AbbVie's voluntary participation in the federal 340B program. Opp. at 16. As explained below, that is wrong as a matter of takings law: Because Act 358 directly imposes conditions on manufacturers without offering any voluntary benefit of Louisiana's own in exchange, the voluntary-participation doctrine is inapplicable. *See infra* § II. But as a matter of federal *preemption* law, Louisiana's argument is tantamount to a confession of error. If Act 358 indeed increases the price of admission to federal programs above the level Congress has set for drug manufacturers, then it necessarily conflicts with Congress's clear decisions about those conditions of participation.

To resist conflict preemption, Louisiana places significant reliance on *Employees Saving Plan of Mobil Oil Corp. v. Geer*, 535 F. Supp. 1052 (S.D.N.Y. 1982), but that case in fact illustrates

why AbbVie is right. *Geer* was an ERISA case. *Id.* at 1056. The preemption proponents argued that ERISA overrode a state's traditional spousal-property-rights rules. *Id.* *Geer* rejected that argument for a specific reason inapplicable here: It held that the state's spousal-rights rules "cannot do substantial damage to any major federal interest" because no such federal interest was present. *Id.* Critically, the court distinguished ERISA from other federal laws that, like the 340B statute, "served major federal goals" and therefore had preemptive effect. *Id.* at 1055-56. One such law the court referred to was the Railroad Retirement Act (RRA), which the Supreme Court had previously held *did* preempt state community-property rules because Congress created it to be "a system of federally administered benefits similar to Social Security … [and that] Congress has 'carefully targeted' the benefits to be provided . . . ." *Id.* at 1056. In the RRA, "Congress carefully targeted the benefits created by the . . . Act," "it [was] for Congress to decide how these finite funds are to be allocated" because "[t]he statutory balance is delicate." *Hisquierdo v. Hisquierdo*, 439 U.S. 572, 584–85 (1979). Because ERISA, by contrast, contained no such careful targeting of federal benefits, *Geer* distinguished *Hisquierdo* and declined to apply preemption.

Applying the *Geer* court's framework, Act 358 is preempted because the federal 340B law *does* advance major federal goals through a careful balancing of benefits, and by disrupting that balance, Act 358 "frustrates the congressional objective." *Id.* at 585; *Geer*, 535 F. Supp. at 1055-56. Consider two examples of such congressional calibration with which the Louisiana statute interferes: First, Congress limited the availability of 340B-discounted drugs to a closed list of statutorily enumerated non-profit clinics, and did not make them available to commercial "contract pharmacies," 42 U.SC. § 256b(a)(4), despite knowing how to authorize contract pharmacy arrangements in other legislation. *See Sanofi*, 58 F.4th at 704–05. Act 358 undoes that choice; that is its entire purpose. Second, Congress established a special Administrative Dispute

Resolution panel to resolve disputes between manufacturers and covered entities concerning alleged overcharges—a panel whose authority is so exclusive that it necessarily displaces attempts by covered entities to sue about overcharges in court. *Astra*, 563 U.S. at 117. As explained in greater detail below, *see infra* § I.B.1, the Attorney General has correctly admitted that Act 358 seeks to provide its own judicial remedy for those same overcharges—precisely the thing *Astra* held to be inconsistent with the federal scheme.

Defendants have no real answer to *Astra*; they use only a few sentences in a weak attempt to distinguish it. Opp. at 13; Intervenor Br. at 18. They chiefly point out that *Astra* was not a preemption case, which is true but irrelevant. In *Astra*, the Supreme Court expounded on the exclusive nature of Congress's chosen ADR enforcement mechanism. 563 U.S. at 119–22. In that case, the legal consequence of Congress's remedial scheme was precluding common law suits by covered entities about overcharges; in this case, the consequence is preempting state laws authorizing state attorneys general to sue over the same thing. The logic of *Astra* is controlling.

Louisiana argues there is no conflict with the 340B statute's ADR provisions because an unintentional violation of Act 358 is not redressable under the Louisiana Unfair Trade Practices Act. Opp. at 14. Whether a violation is intentional or not makes no difference to AbbVie's argument. AbbVie's point is that erecting a separate enforcement scheme that purports to overlap, even in part, with HRSA's mandatory and exclusive ADR procedure raises a conflict with Congress's choices. *See Arizona*, 567 U.S. at 409. Act 358 permits the states to enforce supposed violations of the 340B statute through a separate scheme outside of HRSA's control, in direct contravention of *Astra*. 563 U.S. at 117.[3]

[3] Defendants point to *no* cases denying federal preemption in the context of a federal law as comprehensive and calibrated as 340B. None of the State's cases involve a state law that seeks to regulate a similarly comprehensive federal program. *See Lasko v. Consumers Petroleum of Conn., Inc.*, 547 F. Supp. 211, 216 (D. Conn. 1981) (federal law at issue sought to protect franchisees from arbitrary or discriminatory termination of their franchises). The State's

In short, Act 358 intrudes on an exclusively federally occupied field and, unsurprisingly, winds up conflicting with the specific rules Congress made to govern that field. It is therefore preempted.

B. Defendants' Arguments To The Contrary Are Meritless.

Defendants have no persuasive response to the above analysis. Their principal argument is that Act 358 merely regulates *delivery* of drugs and thus does not expand the scope of eligibility for 340B discounts. That is both legally and factually wrong, and Defendants' appeals to the presumption against preemption cannot alter that.

1. Act 358 Intrudes On Federal Regulation Because It Concededly Regulates Price, Not Delivery.

Defendants attempt to recast Act 358 as a regulation of drug delivery, outside the ambit of federal law. Defendants are legally and factually wrong for several independent reasons.

First, the Attorney General has conceded repeatedly in this litigation that Act 358 is aimed at overcharges, not delivery. The admission was not an accident. The Attorney General says so *15 times* in her Answer—a responsive pleading binding on the State.[4] *See McCreary v.*

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reliance on *Evans v. Loveland Auto. Invs., Inc*, 632 F. App'x 496 (10th Cir. 2015), is especially misplaced. *Evans* is not a preemption case. Instead, the *Evans* Court considered whether a party can enjoy *double recovery* under the Fair Labor Standards Act and the Colorado Wage Claim Act. *Id.* at 497. And Intervenor-Defendant affirmatively cites to just two cases in its entire section on conflict preemption, choosing instead to spend its time discussing Plaintiff's reliance on *Sanofi*. Intervenor Br. at 19-21. And notably, the cases Intervenor-Defendant relies on are (1) the Arkansas *PhRMA* case that is inapposite here for the reasons explained in Section I.C. below, and (2) a Fifth Circuit case where the Court found the state law conflicted with the federal law for the very reasons that apply here. *See Aldridge v. Miss. Dep't of Corrs.*, 990 F.3d 868, 875 (5th Cir. 2021) (holding a state tort law preempted by the Fair Labor Standards Act because "the purposes of the two laws overlap with each other and thus the federal law must control").

[4] *See* Answer ¶ 66 (Louisiana's complaint with manufacturers' 340B contract-pharmacy policies is that they "result[] in Plaintiffs overcharging covered entities for 340B drugs."); *id.*¶ 7 (noting a supposed "sharp increase in overcharges to covered entities following the implementation of such policies"); *id.* ¶ 44 ("It is also admitted that the federal 340B statute provides for the '[s]elective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program…' and also directs the HHS Secretary to promulgate regulations for the establishment and implementation of 'an administrative process for the resolution of claims by covered entities that they have been overcharged for [340B] drugs'"); *id.*¶ 62 ("Answering further, Members of Congress have asked HSRA to institute enforcement actions against pharmaceutical manufacturers ... that unilaterally impose policies that result [in] overcharges to covered entities for 340B drugs."); *id.* ¶ 64 ("Defendant admits that Plaintiffs have refused to deliver 340B drugs to contract pharmacies unless covered entities pay more than the mandated 340B price . . . Defendant

Richardson, 738 F.3d 651, 659 n.5 (5th Cir. 2013). Despite AbbVie's arguments in its opening brief, neither Defendant has *any* response in its opposition—because there is nothing to say. The State has admitted Act 358 is directed at an *undisputedly federal* end—the proper price of 340B drugs, not the method of their delivery—and that ends this case.

Second, Act 358 is not a mere delivery regulation. One could imagine a *bona fide*, generally applicable state regulation that would not run afoul of federal preemption. If Louisiana required all medicines in the state to be transported in temperature-controlled trucks inspected by the state's DMV, *that* would be a regulation of delivery and would not intrude on any federally regulated field or conflict with federal law. Act 358 is not that kind of law.

Act 358 does not regulate how prescription drugs are to be *delivered* to pharmacies like CVS and Walgreens. As AbbVie previously explained, there is no dispute that pharmacies across Louisiana can acquire AbbVie's and other manufacturer's drugs and have those drugs delivered to them through ordinary distribution channels. *See* Opening Br. at 29. Instead, Act 358's *raison d'etre* is to provide an unlimited amount of contract pharmacies access to manufacturers' drugs *at the federal 340B price*. On its face, Act 358 purports to regulate only *340B-discounted* prescription drugs. *See* La. Stat. Ann. § 40:2884 (forbidding manufacturers from interfering with "the acquisition of a 340B drug by, or delivery of a 340B drug to" contract pharmacies); *id.* § 40:2882

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denies that Plaintiffs have any lawful right to charge covered entities more for 340B drugs than required under their PPA...."); *id.* ¶ 65 ("Plaintiffs have transmitted correspondence to covered entities stating that Plaintiffs will not deliver 340B drugs purchased by a covered entity to contract pharmacies unless the covered entity pays more than the mandated 340B price...."); *id.* ¶ 67 ("[R]egardless of any 'commitments' Plaintiffs have made, their policies regarding contact pharmacies have resulted in overcharging covered entities for 340B drugs"); *id.* ¶ 71 ("[T]he federal government sent Plaintiffs correspondence stating that AbbVie's internal policies relating to contract pharmacies had resulted in the manufacturer overcharging covered entities for 340B drugs in direct violation of the 340B statute." (internal quotations omitted)); *id.* ¶ 72 (same); *id.* ¶ 74 (same); *id.* ¶ 76 (same); *id.* ¶ 98 ("Plaintiffs do not have a constitutional right to adopt internal policies that result in overcharging entities for 340B drugs...."); *id.* ¶ 99 ("the specific policies implemented by Plaintiffs have resulted in Plaintiffs overcharging covered entities for 340B drugs in direct violation of the federal 340B statute."); *id.* ¶ 100 (same); *id.* ¶ 131 ("Answering further, the Third Circuit's decision in *Sanofi Aventis* did not consider Plaintiffs' policies, nor did it find that policies that result in overcharging covered entities for 340B drugs are lawful under the federal 340B statute.").

(defining "340B drug" as "a drug that has been subject to any offer for reduced prices by a manufacturer pursuant to 42 U.S.C. 256b"). In the 340B context, pricing and distribution are inextricably linked; there is no "340B drug" without the "340B price."

Here again, the Attorney General has conceded the point. She explains in her submitted Answer and brief in a prior case that Act 358 is aimed at requiring "manufacturers to offer drugs to an unlimited number of contract pharmacies," Cross-Motion for Summ. J., *AstraZeneca Pharms. LP v. Landry*, No. 6:23-cv-01042-RRS-CBW (W.D. La. Dec. 15, 2023) (ECF No. 43) ("Att'y Gen. AZ Br."), at 21, so that covered entities will earn more "revenue," *id*. at 5, and not be "overcharg[ed]," Answer ¶ 66. Exactly so. But who gets access to drugs at the federal 340B-discounted price, and how alleged overcharges under the 340B program are to be addressed, are the *explicit* concerns of the federal 340B statute. *See* 42 U.S.C. § 256b(a)(1) (providing for reduced drug prices for "covered entit[ies]"); *id.* § 256b(a)(4) (setting forth exhaustive list of covered entities); *id.* § 256b(a)(5)(B) (prohibiting covered entities from reselling 340B drugs); *id*. § 256b(d)(3) (subjecting covered entities' violations of reselling prohibition to administrative dispute resolution). Louisiana has no business regulating those subjects.

A simple hypothetical example lays bare both (i) the state's sleight of hand in attempting to disguise Act 358 as merely regulating delivery and (ii) the obvious conflict between Act 358's plain language and the 340B program's centralized enforcement scheme. Assume a manufacturer agrees to transfer its drugs ordered by a particular covered entity to all of that covered entity's contract pharmacies, *but* only if the price charged for the drugs is something greater than the 340B price. The manufacturer agreed to the delivery, transfer, or distribution of its drugs to the contract pharmacy. By refusing to offer the 340B price on the transfer to this covered entity's contract pharmacies, however, under the plain language of Act 358, the manufacturer's actions "deny,

restrict, prohibit [and] interfere" with the "acquisition" or "delivery" of a "340B drug" (i.e., drugs purchased at the 340B price) by a contract pharmacy. Yet under the state's theory where Act 358 regulates delivery but not price, Act 358 should not be implicated by the manufacturer's policy.

Under this hypothetical, the manufacturer has allowed the transfer of its products to the contract pharmacy, so the only bona fide question is whether the price offered by the manufacturer is an overcharge in excess of the 340B price. It is undisputed that the question of an overcharge is exclusively governed by the centralized enforcement scheme set forth in the 340B statute. It is possible HRSA may believe that a manufacturer has violated its obligations under the 340B program and decide to pursue enforcement. It is similarly possible the manufacturer may have reasonable defenses for its policy. But under Act 358, a manufacturer must now defend itself both against HRSA's enforcement *and* a state law proceeding, leading to conflicting results. That is because it is nearly impossible to require transfers of 340B-priced drugs to third party pharmacies without also regulating what price must be offered on those drugs.

Third, the undisputed facts show that contract-pharmacy mandates are about private wealth transfers, not delivery. *See Wos v. E.M.A. ex rel. Johnson*, 568 U.S. 627, 637 (2013) (holding that a "proper [preemption] analysis requires consideration of what the state law in fact does, not how the litigant might choose to describe it."). As the federal official in charge of administering the 340B program has explained to another federal court, under the replenishment model, drug delivery is *disconnected* from 340B pricing. *See* Ex. 2, Pedley Decl. ¶¶ 3–11. As Rear Admiral Pedley admits, and AbbVie's attached declaration confirms, contract pharmacies dispense so-called 340B drugs from "their general inventories"—*i.e.*, from the stock of drugs that were already delivered to the pharmacy through commercial purchases. *See* Ex. 1, Scheidler Decl. ¶¶ 4, 5. After that, as an accounting matter, the contract pharmacies attempt to link prior sales to some covered

entity with which the contract pharmacy has an arrangement. *Id.* ¶ 5. The pharmacy then seeks either money or replenishment stock from the manufacturer at a retroactively discounted price. *Id.* Thus, in the real world, the *only thing* Act 358 effects is the offer price of AbbVie's drugs—not how they are delivered. If Defendants contest those facts on summary judgment, AbbVie is prepared to litigate them at trial, but they are not subject to genuine dispute.

In addition, however, the undisputed facts show that the kinds of contract pharmacy arrangements Act 358 mandates produce *massive* increases in the volume of drugs to which 340B pricing has been applied. *Id.* ¶¶ 14, 15. After those arrangements first became common, the size of the 340B program exploded. It went from a small adjunct to Medicare and Medicaid to the second largest federal drug program—one larger than *all* of the specific Medicare and Medicaid programs in existence when the 340B program was created. Opening Br. at 8. In short, the tail began wagging the dog. No doubt that is one reason the Third Circuit rejected Louisiana's position that federal law always mandated manufacturers' cooperation with commercial contract pharmacies. *Sanofi*, 58 F.4th at 706. As relevant here, that factual reality also shows that Act 358 is not like a regulation of the temperature of delivery trucks. Mandating transfers to contract pharmacies does not change how drugs provided to covered entities will be *transported*; it forces manufacturers to *give away more drugs at discounted prices to different people*. Quite obviously, that is why Louisiana cares about Act 358 in the first place: The state is not concerned that drugs are being misdelivered; it wants commercial pharmacies to get more of AbbVie's property essentially for free.

Fourth, even if Act 358 was solely about delivery, the 340B statute is *not* silent about delivery. The text of the 340B statute shows that Congress explicitly spoke to distribution. For starters—Congress' precise delineation of who is eligible to receive 340B-discounted drugs in the

first place speaks to delivery. *See, e.g.*, 42 U.S.C. § 256b(a)(1); *id.* § 256b(a)(4). And Congress' explanation of who "shall be responsible for the costs of distribution" of discounted drugs to covered entities from manufactures or through a "distribution" program of "prime vendors" HHS "shall establish[]" further speaks to delivery. *Id.* § 256b(a)(8). And speaking to distribution *again*, Congress explained how discounted drugs could be further distributed by covered entities—only to the covered entities' patients. *Id.* § 256b(a)(5)(B) ("With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity."). Defendants thus mischaracterize the 340B program by arguing it is silent on delivery.[5]

For all those reasons, Defendants' appeals to congressional "silence" about delivery are unavailing. Congress was not silent about who is entitled to the benefit of 340B pricing, or how alleged overcharges may and may not be remedied. Because that is precisely what Act 358 regulates—as the Attorney General has repeatedly conceded—it is preempted.

2. Defendants' Remaining Arguments Are Unpersuasive.

Once Defendants' mischaracterization of Act 358 as a mere delivery regulation is laid aside, their remaining defenses of the statute fall away.

First, Defendants are not entitled to any presumption against preemption in this case because Act 358 explicitly depends on a federal law. *See Buckman Co. v. Plaintiffs' Legal Comm.*,

[5] Defendants are also wrong about the legal effect of alleged congressional "silence." Citing *Sanofi*, Louisiana argues that silence in the 340B statute on distribution demonstrates congressional intent to legislate solely about pricing of 340B drugs. Opp. at 11. But in *Sanofi*, the Third Circuit held that the 340B statute *does not* require manufacturers to deliver their discounted drugs to an unlimited number of contract pharmacies, and reasoned that Congress knew how to impose delivery-related requirements but chose not to. 58 F.4th at 704. In other words, *Sanofi* found this statutory silence indicative of the opposite intent the state now urges this Court find hidden in 340B. The Third Circuit went a step further and noted that Congress added specific language to 340B's "statutory neighbor," the Veterans Health Care Act of 1992 when it included a provision for discounted drugs to be delivered through a "commercial entity operating under contract with the agency." *Id.* at 704–05.

531 U.S. 341, 347–48 (2001) (holding there was no presumption against preemption because the state law claims raised by Plaintiff originated from a federal law); *Boyle v. United Techs. Corp.*, 487 U.S. 500, 507–08 (1988) (allowing preemption of state law by federal common law because the interests at stake are "uniquely federal" in nature); *Forest Park II v. Hadley*, 336 F.3d 724, 731–32 (8th Cir. 2003) (holding there was no presumption against preemption in part because the state law at issue sought to regulate participation in a federal program). By its terms, Act 358 could not exist absent the 340B program, which is referenced nearly forty times in the four and half pages of the law's text. *See* La. Stat. Ann. § 40:2882(1), (2) ("Definitions."); *see Buckman Co.*, 531 U.S. at 350–53 (preempting a state's fraud claim because it "exist[ed] solely by virtue of the" disclosure provision of the federal law).

Indeed, the federal 340B program is doubly federal. Participation in the 340B program is a condition of participation in Medicare and Medicaid, two other federal programs. 42 U.S.C. § 256b(a). Maintaining a harmonious balance between the sets of programs is a dominant federal interest. *See Witty v. Delta Air Lines, Inc.*, 366. F.3d 380, 385 (5th Cir. 2004) (concluding that federal regulatory requirements under the Federal Aviation Act for passenger safety warnings were exclusive because the federal statute "require[d] a delicate balance between safety and efficiency" and the "interdependence of these factors requires a uniform and exclusive system of federal regulation if the congressional objectives underlying the [federal statute] are to be fulfilled" (quoting *City of Burbank v. Lockheed Air Terminal Inc.*, 411 U.S. 624, 638–39 (1973))); *see also Leslie Miller, Inc. v. Arkansas*, 352 U.S. 187, 190 (1956) (holding that state laws seeking to impose licensing requirements on federal contractors were preempted by federal law).

Defendants contend that a presumption against preemption applies because regulation of pharmacy practice is within the police powers of the states. Opp. at 7–8; 18; Intervenor Br. at 3–

4; 10–11. Pharmacy practice is not relevant here. Act 358 does not regulate the practice of pharmacy; it imposes additional terms and conditions on drug manufacturers' 340B arrangements with the federal government.

That suffices to distinguish the cases the State cites[6] for the proposition that States have broad police powers in "regulating the administration of drugs by the health professions." *See Whalen v. Roe*, 429 U.S. 589, 603 n.30(1977); *Douglas v. Dobbs*, 419 F.3d 1097, 1102 n.3 (10th Cir. 2005). At issue in *Whalen* was whether New York may record the names and addresses of persons who received certain drug prescriptions, 429 U.S. at 589; *Douglas* was a § 1983 action over a police search of prescription records, 419 F.3d at 1099. Neither is remotely like this case. Nor, for that matter, is *Pharmaceutical Care Management Association v. Wehbi*, 18 F.4th 956, 964 (8th Cir. 2021), which concerned two North Dakota state laws regulating pharmacy benefits managers and how they manage prescription-drug benefits on behalf of health-insurance plans.[7] Act 358 provides absolutely no regulation of how the pharmacies are managing, handling, or recording drug prescriptions. It has nothing to do with "pharmacy practice."

Second, Intervenor contends that Congress knows how to preempt state health laws and must have meant not to do so here. Intervenor Br. at 12-13. That argument has no merit because Act 358 is not a state health law. The law purports to regulate private transactions and the transfer

[6] Intervenor-Defendant does not conduct any analysis to argue there is a presumption against preemption. Intervenor instead relies on the conclusory statement that there is a presumption against preemption in areas of traditional state regulation, without any explanation of why that is the case here. Intervenor Br. at 3–4; 10–11.

[7] Imagine if Congress created a new federal program designed to help the homeless and poor by requiring American farmers to give away their produce at deeply discounted prices to inner-city homeless shelters as a condition of participating in federal farm programs. Over time, instead of giving the produce to the poor and homeless, however, the shelters find a way to generate windfall profits for their own benefit by contracting with high-end supermarkets in affluent communities, which sell the farmers' produce at non-discounted prices to wealthy customers. Imagine also that the courts determine, quite properly, that the federal statute does not require farmers to play along with that abuse. If a state were to enact its own legislation forcing farmers to give away their produce at the federally discounted price to the high-end supermarkets, that legislation would be obviously preempted. It would make no difference that the regulation of supermarkets or the delivery of produce are traditionally subjects of state and local regulation.

of title to private property. In any case, when Congress wants to permit states to augment federal Medicare and Medicaid rules, it knows how to say so. Congress has repeatedly called for federal programs to specifically involve or incorporate state law—but chose not to do so for 340B. *See, e.g.*, 42 U.S.C § 1396a (State plans for medical assistance); § 1396c (Operation of State plans); § 1396g (State programs for licensing of administrators of nursing homes); § 1396h (State False Claims Act requirements for increased State share of recoveries); § 1396n (Compliance with State plan and payment provisions); § 1396o-1 (State option for alternative premiums and cost sharing); § 1396u-7 (State flexibility in benefit packages); § 1396w-3 (Enrollment simplification and coordination with State health insurance exchanges); § 1396w-4 (State option to provide coordinated care through a health home for individuals with chronic conditions); § 1396w-4a (State option to provide coordinated care through a health home for children with medically complex conditions); § 1396w-6 (State option to provide qualifying community-based mobile crisis intervention services). The proper inference from congressional silence about state regulation in the 340B sphere is that Congress did not intend to allow it at all.

C. The Eighth Circuit's Decision in *Pharmaceutical Research & Manufacturers of America v. McClain* Is Distinguishable And, In Any Event, Incorrect.

Defendants may rely on the Eighth Circuit's recent decision in *Pharmaceutical Research and Manufacturers of America v. McClain*, 2024 WL 1061438 (8th Cir. Mar. 12, 2024), but that decision cannot save Act 358. The *PhRMA* case is both legally and factually distinguishable, and its poorly reasoned analysis should not influence the outcome of this case.

In *PhRMA*, the Eighth Circuit rejected a preemption challenge to an Arkansas law requiring pharmaceutical manufacturers to provide their drugs to pharmacies that contract with a covered entity. Ark. Code Ann. § 23-92-604(c) ("A pharmaceutical manufacturer shall not (1) Prohibit a pharmacy from contracting or participating with an entity authorized to participate in 340B drug

pricing by denying access to drugs that are manufactured by the pharmaceutical manufacturers; or (2) Deny or prohibit 340B drug pricing for an Arkansas-based community pharmacy that receives drugs purchased under a 340B drug pricing contract pharmacy arrangement with an entity authorized to participate in 340B drug pricing."). The court of appeals reasoned that, because the 340B program is silent about delivery of drugs to patients, Congress did not intend to preempt the field; and where the contract pharmacies are agents of the covered entities and do not themselves purchase the drugs and take title to them, there is no interference with the closed federal system. *PhRMA*, 2024 WL 1061438, at *4. And it concluded Arkansas's enforcement scheme did not contravene HRSA's exclusive enforcement authority because it ensures only that covered entities can utilize contract pharmacies, without addressing discounted pricing. *Id.* at *5.

For several reasons, this Court should not follow that decision. ***First***, although the Eighth Circuit concluded that the Arkansas statute concerned drug delivery and not price, Act 358 is not a delivery regulation for the reasons explained above. Notably, the *PhRMA* case did not involve a binding admission from the state that its legislation was designed to address overcharges under the federal 340B law. *See supra* § I.B.1.

Second, the Eighth Circuit found it significant that covered entities and contract pharmacies enjoyed an agency relationship. That condition (even assuming it is present in Arkansas) is conspicuously absent here. An agency relationship requires that the principal have the legal power to control the agent's activities. *See Wood v. Holiday Inns, Inc.*, 508 F.2d 167, 172 (5th Cir. 1975) ("A principal-agent relationship is said to exist if the alleged principal reserves the right of control over the conduct and activities of the purported agent."). And normally, as fiduciaries, agents must not commingle their property with their principal's. *See, e.g.*, *United States v. Riley*, 621 F.3d 312, 323 & n.15 (3d Cir. 2010) ("[A] fiduciary is prohibited from acting

to enrich himself on behalf of the principal."); *Hunter v. Shell Oil Co.*, 198 F.2d 485, 490 (5th Cir. 1952) ("A fiduciary is allowed no such latitude with his principal's property."). Act 358 does not require *any* agency relationship to be present between a contract pharmacy and a covered entity to trigger the Act's requirements. Nor is there any evidence that any such agency relationship exists between covered entities and contract pharmacies in Louisiana. Ex. 1, Scheidler Decl. ¶¶ 11, 12.

Third, the Eighth Circuit emphasized that covered entities maintain title to 340B-discounted drugs held by contract pharmacies. Again, Act 358 does not require any such maintenance of title—though it easily could. *Compare* 61 Fed. Reg. 43,549-01 at 43,552 ("The contract pharmacy does not purchase the drug. Title to the drugs passes to the covered entity.") *with* La. Stat. Ann. § 40:2881 *et seq.* (providing no such assurance). In any case, covered entities do not maintain title. As explained above, under the replenishment model, 340B-discounted drugs are mixed with a contract pharmacy's "general inventories"—*i.e.*, its inventory of chattels over which the *pharmacy*, not the covered entity, maintains title. *See* Ex. 1, Scheidler Decl. ¶ 4; *see also* Ex. 2, Pedley Decl. ¶¶ 3–11. Which specific units of medicine are to be treated as 340B drugs is not determined until after those units have already been sold to a pharmacy customer from the general inventory of the pharmacy. Ex. 1, Scheidler Decl. ¶ 5. A covered entity has no legal title to drugs resting in, and later dispensed from, the pharmacy's general inventory. *See* La. Civ. Code Ann. art. 2457 ("When the object of a sale is a thing that must be individualized from a mass of things of the same kind, ownership is transferred when the thing is thus individualized according to the intention of the parties.").

Fourth, Act 358 imposes far more severe restrictions on manufacturers who fail to accommodate drug orders by for-profit pharmacies than the Arkansas statute does. Even for the most serious violation, the Arkansas statute limits fines to $50,000 in a six-month period in

aggregate. *See* Ark. Code Ann. § 23-66-210(a)(1). Act 358, by contrast, not only has no limit on fines, *see* La. Stat. Ann. § 51:1416, but also authorizes such harsh penalties as termination of the right to do business in the state, *see id.* § 51:1408. These differences in the enforcement provisions of Act 358 and Arkansas Act 1103 are particularly noteworthy given *Astra*'s holding that spreading the enforcement burden of the 340B program would frustrate Congress' purpose. *Astra*, 563 U.S. at 119. While the Arkansas statute limits noncompliance penalties to a comparatively small fine, Act 358's remedial scheme allows for fines, investigative demands, restitution, revocation of licenses or other authority to conduct business, appointment of a receiver, and in some extreme cases, dissolution of Louisiana corporate entities and suspension or termination of foreign corporate entities' right to do business in Louisiana. La. Stat. Ann. § 40:2885; *id.* § 51:1408**.**

Fifth, the Eighth Circuit's decision in *PhRMA* is simply incorrect. Perhaps because it wrongly assumed the existence of legal duties between the covered entity and the contract pharmacy (like an agency relationship and covered entities' maintenance of title to drugs), the Eighth Circuit incorrectly concluded that the Arkansas statute merely regulates the delivery of covered entities' own property. For the reasons explained in Section I.B above, that is not correct—or at the very least, it is not correct in Louisiana.

In short, the Court should evaluate Louisiana's Act 358 on its own terms. The Eighth Circuit's *PhRMA* decision does not bind this Court, and its reasoning depends on factors not present here. That decision cannot alter the reality that Act 358 is an unconstitutional attempt to alter Congress's judgments about how to administer federal healthcare programs.

II. ACT 358 EFFECTS AN UNCONSTITUTIONAL TAKING.

Even if not preempted, Act 358 would remain unconstitutional for a second reason: It is a command to transfer AbbVie's property to other private parties, in violation of the Takings Clause. Defendants do not seriously dispute (1) that Act 358 "takes property from A and gives it to B,"

Opening Br. at 36 (quoting *Calder v. Bull*, 3 U.S. (3 Dall.) 386, 388 (1798)); or (2) that Act 358 serves no public use known to either the United States or Louisiana constitutions, Opening Br. at 38. As a result, Act 358 effects "[a] purely private taking" that "serve[s] no legitimate purpose of government and would thus be void." *Hawaii Hous. Auth. v. Midkiff*, 467 U.S. 229, 245 (1984).

The State attempts to avoid the Takings Clause by pointing to two inapplicable doctrines. ***First***, the State contends AbbVie's "voluntary participation" in the federal 340B program means that AbbVie has consented to conditions attached to that program, including Act 358. As explained above, that argument functions as a concession that Act 358 attempts to alter the conditions of a federal program, making it preempted. But as a Takings Clause matter, the argument is simply wrong: Even if the *federal* 340B statute is not a taking because it conditions federal benefits on compliance with 340B rules, *Louisiana* has not conferred any voluntarily accepted benefits on AbbVie to which Act 358 is attached. ***Second***, the State claims that Act 358 is subject to lesser scrutiny under the regulatory takings doctrine, but that is also incorrect. Act 358 forces AbbVie to deliver 340B drugs to an unlimited number of contract pharmacies, depriving AbbVie of the "entire bundle of property rights" in those drugs, rendering it a per se physical taking. *Horne v. Dep't of Agric.*, 576 U.S. 350, 361 (2015) (internal quotations omitted).[8]

1. AbbVie Does Not Voluntarily Participate In Act 358.

Louisiana contends that because AbbVie voluntarily participates in the *federal* 340B program, they have impliedly volunteered to participate in the *state*'s Act 358. Opp. at 17. That is legally wrong. Under certain circumstances, voluntarily accepting a government benefit in exchange for giving up property rights can extinguish a takings claim against the government who

[8] Intervenor-Defendant attempts to avoid a takings analysis by arguing that Act 358 does not regulate drug prices. Intervenor Br. at 21-23. For the reasons discussed extensively in Section I above, that is incorrect.

conferred that benefit. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1007 (1984). Even then, there are limits. As the Supreme Court has explained, "[u]nder the well-settled doctrine of 'unconstitutional conditions,' the government may not require a person to give up a constitutional right—here the right to receive just compensation when property is taken for a public use—in exchange for a discretionary benefit conferred by the government where the benefit sought has little or no relationship to the property." *Dolan v. City of Tigard*, 512 U.S. 374, 385 (1994); *see also Horne*, 576 U.S. at 364–67 (rejecting the government's voluntary exchange argument and reasoning that the government cannot turn a per se taking into a governmental benefit).

That voluntary-participation doctrine may or may not protect the *federal* 340B statute from running afoul of the Takings Clause. Had Congress simply commanded drug manufacturers to transfer their property to covered entities, that would be unconstitutional. *Nollan v. California Coastal Comm'n*, 483 U.S. 825, 831 (1987) ("Had California simply required the Nollans to make an easement across their beachfront available to the public on a permanent basis in order to increase public access to the beach, rather than conditioning their permit to rebuild their house on their agreeing to do so, we have no doubt there would have been a taking."). But instead, Congress conditioned manufacturers' access to federal Medicare and Medicaid benefits on compliance with the requirements of the federal 340B statute. *See* 42 U.S.C. §§ 256b(a); § 1396r–8(a)(1). That bargain—access to federal programs in exchange for property—is the only reason Congress could be permitted to force manufacturers to transfer their drugs to another private party.[9]

None of that, however, helps Louisiana because it is differently situated than the federal government. As Louisiana freely admits, "Act 358 imposes separate requirements on AbbVie" apart from those required by the federal 340B program. Opp. at 17; *see also id.* at 18–19 ("[I]t is

[9] AbbVie does not concede that participation in Medicare and Medicaid is genuinely voluntary.

not the federal government but the state of Louisiana that is requiring AbbVie and other drug companies to ensure that the 340B drug discount applies when drugs purchased by 340B entities are delivered to contract pharmacies."). Because those "separate requirements" were not prescribed by Congress, they are not conditions of AbbVie's voluntary participation in federal Medicare and Medicaid programs.

Nor are Act 358's requirements conditions of voluntary participation in any *state* benefit program. Louisiana forthrightly acknowledges that: The only benefits Louisiana points to are the "profits from [AbbVie's] participation in Medicare and Medicaid," which are not conferred by Louisiana, but by Congress. Opp. at 21. The voluntary-participation doctrine is thus not available to Louisiana because the state provides "no additional benefit" to which Act 358's requirements are attached. *See Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1232 (D.C. Cir. 2023).

Virginia Hospital & Healthcare Association v. Roberts, 671 F. Supp. 3d 633 (E.D. Va. 2023), illustrates the point. There, hospitals and doctors burdened by Virginia's new limits on reimbursement for emergency services sued both the federal and state governments under the Takings Clause. *Id.* at 641. Against the federal government, the plaintiffs challenge their obligations, as Medicare participants, to "treat all patients presenting with an emergency medical condition" under the federal Emergency Medical Treatment and Active Labor Act "EMTALA"), arguing the Act "effect[ed] a *per se* taking." *Id.* at 666. Against the state government, they argued Virginia's certificate of public need ("COPN") program added an additional layer of compulsion because every hospital with acute care services must apply for a COPN certificate if they ever wish to "build, improve, or maintain almost any facility," and they must participate in Medicare and Medicaid to be eligible for those certificates. *Id.* at 667.

The *Virginia Hospital* court concluded that the two governments—one of which rewarded the plaintiffs with benefits while the other did not—were differently situated. According to the court, the *federal* government was clear of any takings liability, because "plaintiffs cannot demonstrate a taking based on an obligation arising under a federal program in which they voluntarily participate." *Id.* at 666. Nevertheless, the court believed the *state* law was likely unconstitutional: "[T]hose *state law* COPN requirements have no bearing on whether providers' participation in Medicaid and Medicare are voluntary as a matter of *federal* law." *Id.* Where the state law forced plaintiffs to turn over property without providing any benefit in exchange, the court determined that "Virginia legally compel[led] any healthcare system with an acute care hospital in Virginia to participate in Medicare and Medicaid," meaning the plaintiffs can turn to "state court to seek just compensation." *Id.* at 667, 669. In other words, a state cannot freeride on the federal government's extension of benefits in an effort to legitimatize its own taking of private property.

Louisiana's failure to provide any additional, voluntarily accepted benefit in exchange for Act 358's conscription of private property also distinguishes *Minnesota Association of Health Care Facilities, Inc. v. Minnesota Department of Public Welfare*, 742 F.2d 442 (8th Cir. 1984). In that case, a plaintiff nursing home sued the Minnesota state government over obligations related to the "state's Medicaid program." *Id.* at 444–46. The court held the plaintiff had no takings claim against Minnesota because it was "only through voluntary participation in the state's Medicaid program that a nursing home" became subject to the challenged obligations in the first place. *Id.* The situation here is different: Act 358's concededly separate requirements are not attached to any state program in which AbbVie voluntarily participates, and Louisiana does not argue otherwise.

Louisiana cites no case where a state law purported to alter or expand the conditions of participation in a federal program and then successfully relied on the federal benefits to avoid Takings Clause scrutiny. Instead, Louisiana's brief extensively discusses cases like *Eli Lilly & Co. v. United States Dep't of Health & Hum. Servs.*, which upheld the *federal* 340B statute on voluntary participation grounds, 2021 WL 5039566, at *21 (S.D. Ind. Oct. 29, 2021), and *Garelick v. Sullivan*, 987 F.2d 913, 916–17 (2d Cir. 1993), which similarly rejected a claim against the federal government. In *Garelick*, the Second Circuit held anesthesiologists who "voluntarily choose to provide services" in a Medicare program "do not have a viable takings claim" against the federal government. *Id.* ("[I]t is New York State—which is not a party to this action—that indirectly compels anesthesiologists to treat Medicare patients and thus submit to price regulations, not the federal government.").[10] None of those cases suggest Louisiana can piggyback on federal law to take advantage of the voluntary-participation doctrine, while simultaneously purporting to alter the *terms* of the deal between AbbVie and the federal government.

Finally, Louisiana suggests that the "regulated" nature of the healthcare industry gives it more freedom to impose conditions on federal Medicare and Medicaid participation. Opp. at 20. That is wrong. AbbVie has property rights in the drugs it makes. *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982) ("Property rights in a physical thing have been described as the rights to possess, use and dispose of it.") (internal quotations omitted). In this

[10] Other cases are to the same effect. *See Baker Cnty. Med. Servs., Inc. v. U.S. Atty. Gen.*, 763 F.3d 1274, 1279 (11th Cir. 2014) (no takings claim against the federal government for a hospital that voluntarily "opted into Medicare and became subject to [the Emergency Medical Treatment and Active Labor Act]"); *Whitney v. Heckler*, 780 F.2d 963, 972 & n.12 (11th Cir. 1986) (physicians cannot sue the federal government for taking because they voluntarily chose to "treat Medicare patients" when they were "not required to" do so); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875–76 (7th Cir. 1983) (hospital had no takings claim against the federal government, because "[e]ven those hospitals that have an obligation to participate in the Medicare program . . . made a voluntary choice to accept both the obligations and the benefits of Hill-Burton funding."); *Burditt v. U.S. Dep't of Health & Hum. Servs.*, 934 F.2d 1362, 1376 (5th Cir. 1991) (hospitals cannot argue EMTALA effects a taking because "[o]nly hospitals that voluntarily participate in the federal government's Medicare program must comply with EMTALA).

country, the use of property can be regulated; but those regulations cannot take the form of uncompensated *takings* of private property for the benefit of other private parties. U.S. Const., amend. V. And as the Supreme Court has made clear, the general right to buy and sell property is not a benefit to which confiscatory conditions can be attached. *See Horne*, 576 U.S. at 366 ("Selling produce in interstate commerce, although certainly subject to reasonable government regulation, is similarly not a special governmental benefit that the Government may hold hostage, to be ransomed by the waiver of constitutional protection."). As with "the right to build on one's own property," "even though its exercise can be subjected to legitimate permitting requirements[, it] cannot remotely be described as a 'governmental benefit.'" *Nollan*, 483 U.S. at 833 n.2; *see also, Philip Morris, Inc. v. Harshbarger*, 159 F.3d 670, 677 (1st Cir. 1998) ("Permitting a company to continue conducting business within a state, while a benefit of sorts, lacks sufficient substance to create a [voluntary] exchange.").

Even assuming Louisiana did extend a benefit to AbbVie in exchange for its giving away 340B drugs at deeply discounted prices, Louisiana has not shown that the state has a legitimate interest that "bears an 'essential nexus' and 'rough proportionality' to the impact of the proposed use of the property." *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 161 (2021) (quoting *Dolan*, 512 U.S. at 386, 391). The state may have a legitimate interest in making drugs affordable to its residents, but Act 358 makes national pharmacy chains the primary beneficiaries of the law. Such mismatch between means and end falls far short of the Constitution's mandate that a government "may not leverage its legitimate interest in mitigation to pursue governmental ends that lack an essential nexus and rough proportionality to" a property owner's exercise of its property rights. *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 606 (2013).

In short, Louisiana cannot point to any voluntary exchange exempting Act 358 from plenary scrutiny under the Takings Clause.

2. Act 358 Effects A *Per Se* Taking.

Louisiana incorrectly argues that even if Act 358 is subject to the Takings Clause, it is merely a regulatory taking warranting relaxed judicial scrutiny. Under the regulatory takings doctrine, "[a] regulatory restriction on use that does not entirely deprive an owner of property rights may not be a taking." *Horne*, 576 U.S. at 364. But Act 358 is not a regulatory restriction. It is a physical appropriation of plaintiffs' property—a requirement that AbbVie transfer title to its chattels to someone else.

The Attorney General elsewhere has admitted that Act 358 has precisely that confiscatory effect. In her brief in a related case pending before this Court, the Attorney General affirmatively explained that "Act 358 . . . simply requires manufacturers to offer drugs to an unlimited number of contract pharmacies"—*i.e.*, private third parties—and "reroutes the flow of such drugs" to where the Louisiana legislature wants them to go. Att'y Gen. AZ Br. at 21; *see also* La. Stat. Ann. § 40:2884. When a drug, as directed by Act 358, goes to a contract pharmacy, to whom AbbVie otherwise does not wish to sell, AbbVie loses the "entire bundle of property rights" in that drug, as it can no longer "possess, use and dispose of" the drug as it wishes. *Horne*, 576 U.S. at 360–61 (internal quotations omitted). When a government "directly appropriates private property," that is a *per se* taking. *Id.* at 357. "[W]hen there has been a physical appropriation," courts "do not ask . . . whether it deprives the owner of *all* economically valuable use of the item taken" as in the regulatory-takings context. *Id.* at 363 (emphasis added and internal quotations omitted). Instead, it is just an old-fashioned taking.

Because Act 358 effects a physical taking, it does not matter (as Louisiana claims) that AbbVie is still paid for the drugs required to be delivered to an "unlimited number of contract

pharmacies." Att'y Gen. AZ Br. at 21. That is so for two reasons. ***First***, the government cannot take property for *private* use even if it compensates the property owner; payment therefore does not cure the Takings Clause problem. "[O]nce there is a taking, as in the case of a physical appropriation, any payment from the Government in connection with that action goes, at most, to the question of just compensation," not public use. *Horne*, 576 U.S. at 364. Here, there is no valid public use for the reasons explained in AbbVie's opening brief. Opening Br. at 38. Even *Kelo*—the high-water mark for expansive understandings of public use—forbids taking private property "to benefit a particular class of identifiable" private parties like contract pharmacies, *Kelo v. City of New London, Conn.*, 545 U.S. 469, 478 (2005), and that is precisely what Act 358 does. ***Second***, it is undisputed that the *amount* AbbVie is paid for drugs Act 358 requires to be transferred does not represent the fair market value of those drugs as the Takings Clause would require for just compensation, *see Horne*, 576 U.S. at 368–69, but instead requires steeply discounted product with prices often as low as a penny per unit as set by the 340B statute.

In short, the regulatory takings doctrine cannot save Act 358. However flexible that doctrine may be, it cannot be applied to abrogate a property owner's "right to retain the interests and exercise the freedoms at the core of private property ownership." *Murr v. Wisconsin*, 582 U.S. 383, 394 (2017). Here, Act 358 does not attempt to benefit the public through regulation, but instead enriches for-profit commercial pharmacies seeking to capture the value of AbbVie's property for themselves to the tune of billions of dollars. Opening Br. at 11. And as AbbVie has explained, under the "replenishment model" currently in force throughout the industry, ordinary patients of covered entities do not see any savings from 340B discounts—they pay full price, and CVS and Walgreens keep their money. *Id.* at 8; Ex. 1, Scheidler Decl. ¶¶ 4, 5. But even to the extent Louisiana defends Act 358 as a regulation for the public's general benefit, the government

cannot "forc[e] some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole." Opening Br. at 36. A state cannot fund its healthcare policies by expropriating medicines from particular private parties and forcing those private parties to bear the cost of distributing low-cost medicines throughout the state.

III. ACT 358 IS UNCONSTITUTIONALLY VAGUE.

To the extent Act 358 does not have the meaning discussed above, then it is indecipherable and unconstitutionally vague. When a statute includes an undefined term subject to no meaningful limiting construction, it may be unconstitutionally vague. *Carolina Youth Action Project; D.S. by & through Ford v. Wilson*, 60 F.4th 770, 786 (4th Cir. 2023). Act 358 purports to prohibit "interference" with the acquisition of 340B-priced drugs by a contract pharmacy but supplies no definition of "interference" that an ordinary person can reasonably discern. To make matters worse, Act 358's geographic scope is undefined and unlimited—leaving unclear whether its restrictions apply beyond the state of Louisiana. *Compare Grayned v. City of Rockford*, 408 U.S. 104, 111 (1972) (upholding a statute against a vagueness challenge partly because the statute limited what it forbade with "fixed times" and "at a sufficiently fixed place") *with Carolina*, 60 F.4th at 787 (finding a statute unconstitutionally vague when there were no clarifying terms, like "temporal and spatial" restrictions).

The Attorney General's defenses of the statute are not persuasive. She argues that the "[t]he interpretive principle of *noscitur a socciis* … directs that 'interfere' should be interpreted in association with 'deny, restrict, [and] prohibit,'" and therefore "interfere" is not "unbounded" or "incomprehensible." Opp. at 24–25. But that does not supply meaningful content to the statute. Repeating a set of synonyms for "interfere" does not tell the regulated entities *what counts* as "interference." One can "interfere" with something short of "prohibiting" it altogether, *Carolina*, 60 F.4th at 787, but Act 358 does not say what kind of conduct triggers the statutory prohibition.

Precedent confirms that unexplained prohibitions on "interference" violate the vagueness doctrine. In *Carolina*, for example, the Fourth Circuit invalidated a law as unconstitutionally vague where it made it a crime to "willful[ly] or necessar[ily]" "interfere with or . . . disturb in any way or in any place the students or teachers of any school or college in this State[.]" *Id.* at 786. As here, the vague part of that statute was the prohibition on "interfer[ing]"; the court held that that including "willful or unnecessary" in the statute did nothing to help, and in fact made the vagueness problem "worse, not better." *Id.* Instead, what the statute in *Carolina* lacked was clarifying features that limited the statute's construction, like temporal or spatial restrictions. *Id.* at 786–87. The same issues plague Act 358.

Louisiana's response is unavailing. For starters, the Attorney General's opposition on this point is a cut-and-paste job from the wrong brief. The State refers to AbbVie as "PhRMA" seven times, Opp. at 22, 23, 25, 26, 27, in this section alone. *See also* Opp. at 5, 15 (other references to "PhRMA"). In doing so, the Attorney General criticizes and attacks arguments AbbVie never made. For example, her motion contends that "PhRMA argues that Act 358 is not limited to conduct but also to speech. According to the complaint, Act 358 may 'prevent a manufacturer from publicizing information about unlawful transfers occurring at particular contract pharmacies' or 'prevent manufacturers from filing complaints in the context of the federal system that Congress created for administrative dispute resolution.' Compl. ¶ 112." Opp. at 27. But AbbVie made no such argument. Meanwhile, because the State did not bother to respond to AbbVie's *actual* brief on this point, it has no response to AbbVie's argument that Act 358 is unconstitutionally vague for its lack of clarity as to the geographic scope of the statute. The argument is therefore waived.

In any event, Defendants' arguments are wrong. Both Defendants argue that because Act 358 is economic in nature, it is entitled to a "greater degree of vagueness." Opp at. 22; *see also*

Intervenor Br. at 24. Not so. Although it is true that economic regulations often entail less severe penalties (and therefore sometimes invite less exacting judicial scrutiny), *see Levin v. Com. Energy, Inc.*, 560 U.S. 413, 426 (2010), Act 358 is draconian. Its penalties for noncompliance are quasi-criminal, and include suspension of, or an outright bar on, foreign corporations' right to do business in Louisiana. La. Stat. Ann. § 51:1401-09.

The cases on which Louisiana relies for a relaxed vagueness test are inapposite for that reason. Opp. at 21–22. In *Lafayette City-Par Gov't v. United States*, 622 F. Supp. 3d 257, 265–66 (W.D. La. 2022), the challenged statute related purely to the requirements for obtaining a construction permit, and it contained no penalty scheme. *Id.* And in *Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc*., 455 U.S. 489, 492 (1982), a violation of the statute was "subject to a fine of not less than $10 and not more than $500" per day. *Id.* In other words, the maximum penalty at issue in *Hoffman* was $500 per day. As the *Hoffman* court explained, economic laws express a "greater tolerance of enactments with civil rather than criminal penalties because the consequences of imprecision are qualitatively less severe." *Id.* at 498–99. Here, however, a violation of Act 358 could result in debarment from doing business in the state—a corporate death penalty.

Unlike the Attorney General, Intervenor attempts to defend the geographic-scope problem besetting Act 358, but does not succeed. The cases Intervenor relies upon are unavailing. In *Int'l Soc. for Krishna Consciousness of Atlanta v. Eaves*, the statute contained additional clarifying features and was obviously limited in scope "only to airports." 601 F.2d 809, 831–32 (5th Cir. 1979). Similarly, in *United States v. Bird*, 124 F.3d 667, 683–84 (5th Cir. 1997), the court upheld the statute where the ordinance contained a clear spatial restriction. Intervenor does not, and could not, analogize the laws at issue in these cases to Act 358, which has no similar limiting language.

As written, Act 358's terms may apply to *any* pharmacy in the United States where 340B drugs are dispensed to Louisiana residents. *See* La. Stat. Ann. § 37:1164(38) (defining "Pharmacy" to "mean[] any place located within [Louisiana] where drugs are dispensed and pharmacy primary care is provided, ***and any place outside of [Louisiana]*** where" the same occurs for "residents of [Louisiana]" (emphasis added)); *see* La. Stat. Ann. § 40:2882. Indeed, the Attorney General has clearly stated the point of the law is to permit "unlimited" access to 340B-priced drugs for an unknown number of contract pharmacies like Walgreens, CVS, and others. Similarly, Act 358 contains no geographic scope. *Carolina*, 60 F.4th at 787. As written, Act 358's terms may apply to *any* pharmacy in the United States where 340B drugs are dispensed to Louisiana residents. *See* La. Stat. Ann. § 37:1164(38); *see* La. Stat. Ann. § 40:2882. Here, Act 358 could theoretically reach even the furthest corner of Alaska. If that is indeed the intended meaning of "interfere," then Act 358 is not vague, but it is preempted and violates the Takings Clause. Otherwise, the word "interfere" must bear some other meaning that no one can discern, rendering the statute void for vagueness. Either way, the Act cannot stand.

In sum, Act 358 is unconstitutional thrice over. *First*, it is preempted because it unconstitutionally invades a federally regulated field and stands as an obstacle to accomplishing Congress's objectives. It is universally understood that the object of Act 358 is to codify the argument Louisiana unsuccessfully advanced in the Third Circuit—its interpretation of the federal 340B statute's pricing provisions. In other words, far from being a regulation of drug delivery, Act 358 seeks to expand the availability of 340B pricing beyond what federal law requires. But Louisiana cannot raise the price of admission to federal programs above the level Congress has set. *Second*, Act 358 is a command to transfer AbbVie's property to other private parties, in violation of the Takings Clause. It is not part of any voluntary exchange with Louisiana. *Third*,

to the extent Act 358 does not have the meaning discussed above, then it is indecipherable and unconstitutionally vague.

CONCLUSION

Act 358 is unconstitutional. AbbVie's motion for summary judgment should be granted. Defendants' motion for summary judgment should be denied.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 5th day of April, 2024, I electronically filed the forgoing with the Clerk of Court by using the CM/ECF system. The forgoing has also been served electronically on all known counsel.

By: */s/ Charles M. Jarrell*
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